REMARKS

1. Rejection of Claims 2, 26 and 27 Under 35 U.S.C. § 112, Second Paragraph

Claims 2, 26 and 27 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Initially, the Examiner alleges that claim 2 is unclear as to which nucleic acid molecules encode which enzymes. Although Applicants disagree, and believe that it would be clear to one of skill in the art in view of the specification as filed which nucleic acid molecules encode which enzymes, in order to expedite prosecution of this application, Applicants have amended claim 2. In light of this amendment to claim 2, withdrawal of its rejection under 35 U.S.C. § 112, second paragraph, is believed to be in order and is respectfully requested.

The Examiner also alleges that claims 2, 26, and 27 are indefinite for reciting abbreviations. Applicants respectfully disagree. Applicants need not include full names for abbreviations which are well known to one of skill in the art, and thus terms such as "DNA" need not have the full name "deoxyribonucleic acid" recited in the claims prior to the first recitation of "DNA". Similarly, UDP (uridine diphosphate) and NDP (nucleoside diphosphate) are abbreviations well known and frequently used by one of skill in the art. See for example the attached abstracts for Otero, *J. Biol. Chem. 272(23)*:14690-14694 (1997) (which recites NDP) and Marolda *et al.*, *22(5)*:827-840 (1996) (which recites UDP). Also see page 6, line 1, of the specification as filed.

In light of these remarks, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. § 112, second paragraph.

2. Rejection of Claims 2 and 7-27 Under 35 U.S.C. § 101

Claims 2 and 7-27 have been rejected under 35 U.S.C. § 101 for purportedly lacking patentable utility. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "as probes, the isolation of full-length cDNAs or genes, which would be used to make protein and optionally further usage for mapping and numerous other generic genetic engineering usages." Office Action mailed August 15, 2001, page 4, reiterated by reference in the Official Actions mailed January 29, 2002, July 16, 2002, and April 16, 2003. However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility. Applicants respectfully disagree with this assertion.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for identifying additional genes that encode enzymes associated with the plant sucrose pathway, identifying marker nucleic acid molecules which can be used in methods for determining a level or pattern in a plant cell of an enzyme in a plant sucrose pathway (see for example page 45 of the specification as filed), etc.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.* the claimed nucleic acid molecule may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecule. Rather, the Examiner attempts to undermine the existing utilities by stating that the disclosed uses "are generally applicable to any nucleic acid." Office Action mailed August 15, 2001, at page 4.

In short, the Examiner's rejection, as it pertains to 35 U.S.C. § 101, rests on the premise that because other molecules might be used for the same purpose, the proposed utilities for the claimed molecules are legally insufficient. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renshaw PLC,* 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty,* 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecule encompasses many utilities. Furthermore, Applicants acquiesce that some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecule will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Furthermore, utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir.

1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert,* 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Since the Examiner does not make a credible challenge of the disclosed utilities, this burden has not been met, and the rejection is improper.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 1 under 35 U.S.C. § 101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

3. Rejection of Claims 2 and 7-27 Under 35 U.S.C. § 112, First Paragraph

In the Official Action, at page 5, the Examiner has rejected claims 2 and 7-27 for purportedly not being enabled by the specification, because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection. This rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. In light of this, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

4. Rejection of Claims 2 and 7-27 Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 2 and 7-27 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter not described in the specification in such as way as to reasonably convey to one of skill in the art that the inventors has possession of the claimed invention at the time of filing. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

An adequate written description of a genus of nucleic acids, such as recited in claims 2 and 7-27, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules

(*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner contends that the skilled artisan cannot envision the specification lacks actual sequence information for each of the nucleic acid molecules encoding. Office Action at page 5. According to the Examiner's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every nucleic acid of every sequence encompassed by that claim. Applicants respectfully disagree. The present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others.

In particular, Applicants have provided detailed chemical structures, *i.e.*, the nucleic acid sequences of SEQ ID NOs:11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681 and 2753. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable – they comprise a nucleic acid molecule having the sequence selected from the group consisting of SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681 and 2753. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claims 2 and 7-27 and SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681 and 2753. Thus, claims 2 and 7-27 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

5. Objection to the Specification

The specification has been objected to for purportedly containing embedded hyperlink and/or other form of browser-executable code. Applicants respectfully disagree.

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that on the United States Patent and Trademark

Office website, one cannot click on the hyperlink and be transported to another, potentially commercial, website. This requirement does not exclude the listing of a website that is not present as a hyperlink.

In the Responsive Amendment filed November 14, 2001, Applicants amended the specification to remove the hyperlinks (instead listing the websites using the format www.websitename.html). The Examiner notes this amendment, but purports that this citation is still usable as a hyperlink. Applicants disagree.

Although it is possible to click on this purported "hyperlink" in a Microsoft Word document and be transported to the corresponding website, or even to copy and paste this purported "hyperlink" into the address location in Microsoft Explorer, this purported "hyperlink" would not be usable when placed on the United States Patent and Trademark Office website. For example, a search of the United States Patent and Trademark Office patent database using "www.ncbi.nlm.nih.gov" identified 63 patents citing this website, including USP 6,552,250. In the '250 patent, the citation of this website using the exact format used by the Applicants does not result in a useable hyperlink. Therefore, the citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

In light of these remarks, applicants respectfully request withdrawal of this objection to the specification.

CONCLUSION

Applicants respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. As such, Applicants believe the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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